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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 09/883,848 | 06/18/2001 | Leona E. Ling | CIBT-P01-119 | 9957 |
| 28120 | 7590 | 10/19/2004 | EXAMINER | |
| ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624 | | | FETTEROLF, BRANDON J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|--------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/883,848 | | LING ET AL. | |
| | Examiner | | Art Unit | |
| | Brandon J Fetterolf, PhD | | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,25-27 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 25-27 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1642

Re: Lin *et al.*

Date of priority: 6/18/2001

Response to Amendment

The Amendment filed 09/02/2004 in response to the previous Non-Final Office Action (07/15/2004) is acknowledged and has been entered.

Claims 3-24 and 28-34 are withdrawn from consideration by Applicant.

New claims 35-38 have been added.

Claims 1-2, 25-27 and 35-38 with respect to the structure presented in Exhibit 1 page 3 of the Action (07/15/2004) are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1-2 and 25-27 **remain** rejected and new claims 35-38 are rejected under 35 USC 102(e), as being anticipated by Porter et al. (U.S. Patent No. 6,613,798, 03/30/2000) for reasons of record in the Action mailed 07/15/2004 (page 4) and for the reasons set forth below.

In reference to the previous action which held that the patentably disclosed Hedgehog agonist of interest, Exhibit 1, would inherently promote angiogenesis, Applicants contend (Remarks, 09/02/2004) the Examiner has provided no reference to support the assertion that wound healing is *necessarily* accompanied by an increase in angiogenesis. Applicants argue that wound healing is a complex biological process ... involving a diverse array of processes including cell proliferation, cell differentiation, and inflammation. Applicants further argue that the prior art fails to teach or suggest each and every limitation of the present claims ... directed to methods of promoting angiogenesis by administering an "angiogenic amount" of a hedgehog agonist. Additionally, Applicants contend for inherent anticipation of method claims, if a claimed method comprises steps identical to those of a method practiced in the prior art, and the same result would have been achieved in the prior art method, the accidental or unwitting achievement of that result cannot constitute anticipation. *In re*

Art Unit: 1642

Marshall, 578 F.2d 301, 198 USPQ 344 (CCPA 1978). These arguments have been carefully considered but are not found persuasive. First, the previous rejection was based on the technical reasoning that necessarily flowed from the teachings of the prior art- a Hedgehog agonist that promotes wound healing would inherently promote angiogenesis because “Angiogenesis, the process of sprouting new blood vessels from existing vasculature, ... *is* physiologically important in vascular growth in adult tissues and these processes of vascular growth are required for beneficial processes such as tissue repair, wound healing, ect... (Specification, page 2, lines 10-16).” Secondly, Applicants have not provided evidence to the contrary or established a patentable difference between the method or product used in the prior art and the current pending claims. For example, while Applicants allege that the prior arts’ disclosure of exemplary therapeutic methods, for example in the promotion of wound healing, neither teaches nor suggest administration of an “angiogenic amount” of hedgehog agonist, applicants fail to mention *what* amount of hedgehog agonist is required to achieve an “angiogenic amount”. Thus, any argument alleging that administering an amount of a Hedgehog agonist that promotes wound healing, would not necessarily promote angiogenesis is not pertinent because this says nothing about the amount of a Hedgehog agonist required to promote angiogenesis. Moreover, Applicants have not established in their interpretation of *In re Marshall* for inherent anticipation of method claims, any patentable differences between the claimed method and the method practiced in the prior art. In *Marshall*, the PTO board used the *Physician’s Desk Reference* (PDR) as a basis for a rejection of the applicant’s weight control process. The applicant uses an effective amount of the anesthetic, oxethazaine, to inhibit release of the pancreatic secretory hormones, secretin and pancreozymin, in order to control weight. The PDR, however, teaches using drugs containing the anesthetic oxethazaine to inhibit release of the acid stimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. The court reversed the Board’s rejection and held that the *Physician’s Desk Reference* (PDR) did not teach the use of a compound as a weight control drug. Thus, oxethazaine was used to inhibit two different populations of hormones. Unlike *Marshall*, the hedgehog agonist of interest appears to interact with the same pathway as taught in the prior art. For example, the reference teaches (Column 18, lines 40-43) that small molecules can modulate the signal transduction pathways regulated by hedgehog, patched (ptc), gli and/or smoothened. Similarly, the specification teaches (page 70, lines 34-35) that small organic molecules may agonize hedgehog signal

Art Unit: 1642

transduction via an interaction with but not limited to hedgehog, patched (pct), gli, and/or smoothened. Thus, it would appear that the method steps described in the prior art comprise the same steps and uses the same product as claimed in the instant invention. And, since the product of the prior art appears to be identical to that required by the claims, the methods will inherently lead to the promotion of angiogenesis. Thus, since the product of the prior art has the same chemical structure as that described in the specification, it can be assumed that the product will inherently perform the claimed process. (See MPEP 2112.02). Thus, applicant's arguments have not been found persuasive and the rejection is maintained. Newly added claims 35-38 directed to a method of promoting angiogenesis by administering an "angiogenic amount" of a small organic molecule, which agonizes hedgehog transduction via an interaction with any of hedgehog, patched, gli, or smoothened are rejected for the reasons set forth above.

No claim is allowed.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1642

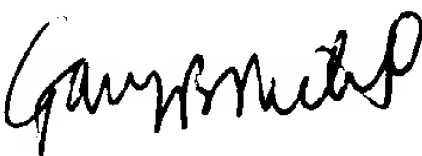
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF


GARY NICKOL
PRIMARY EXAMINER